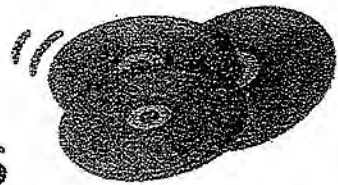


EPA Reg. No. 72159-17

NEW APPLICATIONS



DATE: DEC 01 2016

FILE REG NUMBER: 72159-RT

FEP (OFFIN ENTRY): P JN DEC 01 2016

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

SIG: _____

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

ASSIGN TO PM: AD _____ RD 1 BPPD _____

JACKET TO SHELF (DATA)

PROCESSING REQUEST

Reg #: 11207-17 Decision #: _____

Description: See Serial 1

Material Available Electronically (see PPLS):

☐ Electronic Label/Letter Dated: 3/31/2017

☐ Other: _____

Material Sent (see jacket):

☐ Stamped Label/Letter Dated: _____

☐ Notification Dated: _____

☐ New CSF(s) Dated: _____

☐ Other: _____

Reviewer: Melody Banks

Division: Registration Division/Invertebrate & Vertebrate Branch 3

Phone: (703) 305 5413 Date: 3/31/2017



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

72159-17

Date of Issuance:

3/30/17

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Agrisel Gladiator Place Pack Pellets

Name and Address of Registrant (include ZIP Code):

Agrisel USA, Inc.
c/o Jane Miller
Biologic, Inc.
115 Obtuse Hill Road
Brookfield, CT 06804

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Elyssa Arnold

Elyssa Arnold, Acting, Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)

Date:

3/30/17

2. Be aware that proposed data requirements have been identified in a Work Plan or proposed DCI. For more information on these proposed data requirements, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:
<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>
3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 72159-17."
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated November 29, 2016

If you have any questions, please contact Melody Banks by phone at (703) 305-5413, or via email at Banks.Melody@epa.gov.

Sincerely,



Elyssa Arnold, Acting Product Manager 01
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Outer Container Label
Agrisel Gladiator Place Pack Pellets
11/28/2016

Agrisel Gladiator Place Pack Pellets

[Effective Indoor and Outdoor Control of Norway Rats, Roof Rats, Cotton Rats, Polynesian Rats, House Mice, Eastern Harvest Mice, Golden Mice, and Meadow Voles]

[Kills Norway Rats, Roof Rats, Cotton Rats, Polynesian Rats, House Mice, Eastern Harvest Mice, Golden Mice, and Meadow Voles]

[Norway Rats, Roof Rats, and House Mice usually consume a lethal dose in a single night's feeding, but it may take two or more days from time of bait consumption for them to die. Due to Stop Feed Action rats, mice and meadow voles will cease feeding after consuming a toxic dose.]

[This product is effective against anticoagulant-resistant Norway Rats, Roof Rats, and House Mice.]

[This product may only be used inside and within 100 feet of man-made structures or inside of transport vehicles (ships, trains, or aircraft).]

ACTIVE INGREDIENT:

Bromethalin	
(CAS No. 63333-35-7).....	0.01%
OTHER INGREDIENTS:	99.99%
TOTAL:	100.00%

EPA Reg. No. 72159-XX

EPA Est. No. XXXXX-XX-XXX

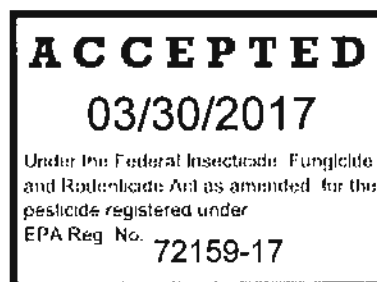
KEEP OUT OF REACH OF CHILDREN CAUTION

Net Contents: 128 x 0.50 ounce (21.3 grams) through
1120 x 0.50 ounce (21.3 grams)

Net Weight: 4 pounds (1.81 kilograms) through
35 pounds (15.88 kilograms)

This Product May Not Be Sold in Packaging that Holds Less Than 4 Pounds of Bait.

Manufactured For:
Agrisel USA, Inc.
P.O. Box 3528
Suwanee, GA 30024



FIRST AID	
HAVE LABEL WHEN OBTAINING TREATMENT ADVICE	
If Swallowed:	<ul style="list-style-type: none"> • Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice.
If in Eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice.
Have product container or label with you when calling a poison control center or doctor for treatment advice.	
TREATMENT FOR PET POISONING	
If animal eats bait, call veterinarian or 1-800-498-5743 at once.	
NOTE TO PHYSICIAN OR VETERINARIAN	
Contains the nerve poison Bromethalin. This is not an anticoagulant type rodenticide. For humans or animals ingesting bait and/or showing poisoning signs (such as muscle tremors, loss of hind limb use, or seizures for animals), limit absorption by either emesis or gastric lavage. Sublethal symptoms, if present, would be the result of cerebral edema and should be treated accordingly through administration of an osmotic diuretic and corticosteroid.	
For 24-hour emergency information on this product, call 1-800-498-5743 (US & Canada) or 1-651-523-0318 (all other areas).	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Keep away from children, domestic animals, and pets. Do not get in eyes, on skin, or on clothing. All handlers (including applicators) must wear long-sleeved shirt and barrier laminate gloves. Any person who retrieves carcasses or unused bait following application of this product must wear barrier laminate gloves.

User Safety Requirements

- Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.
- Remove PPE immediately after handling this product. Wash the outside of barrier laminate gloves before removing them.
- As soon as possible, wash hands thoroughly after applying the bait and before eating, drinking, chewing gum, using tobacco or using the toilet and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to mammals and birds. Dogs and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may also be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash water or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **READ THIS LABEL:** Read this entire label and follow all use directions and use precautions. Use only for the sites, pests, and application methods described on this label.

IMPORTANT: Do not expose children, pets or other non-target animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hooved livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used wherever children, pets, non-target mammals, or birds may have access to the bait placement location.

USE RESTRICTIONS:

This product may only be used to control the following rodent pests in and around man-made structures: Norway rat (*Rattus norvegicus*), Roof rat (*Rattus rattus*), Cotton rat (*Sigmodon hispidus*), Polynesian rat (*Rattus exulans*), House mouse (*Mus musculus*), Eastern harvest mouse (*Reithrodontomys humuli*), Golden mouse (*Ochrotomys nuttalli*), and Meadow vole (*Microtus pennsylvanicus*).

This product must be used in and within 100 feet of man-made structures constructed in a manner so as to be vulnerable to commensal rodent invasions and/or to harboring or attracting rodent infestations. Examples of such structures include homes and other permanent or temporary residences, food processing facilities, industrial and commercial buildings, trash receptacles, agricultural and public buildings, transport vehicles, (ships, trains, aircraft), docks and port or terminal buildings and related structures around and associated with these sites. Fence and perimeter baiting, beyond 100 feet from a structure as defined above, is prohibited.

This product must not be applied directly to food or feed crops.

Do not use this product in sewers.

Do not broadcast bait.

Do not place bait near or inside of ventilation duct openings.

Do not contaminate water, food, feed, food- or feed-handling equipment, milk- or meat-handling equipment, or surfaces that come into direct contact with food. When used in USDA-inspected facilities, this product must be applied in tamper-resistant bait stations.

Burrow baiting with Agrisel Place Pack Pellets is prohibited.

Do not sell this product in individual containers holding less than four (4) pounds of bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats, mice or meadow voles will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings, in corners and concealed places, between floors and walls, or in locations where signs of these rodents have been seen. Protect bait from rain or snow. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

The active ingredient in this product is different from anticoagulant rodenticides. Individual rats, mice and meadow voles cease feeding after consuming a toxic dose.

Rats: Apply 2 to 12 place packs at each placement location. Space placements at intervals of 15 to 30 feet in infested areas.

Mice and Meadow Voles: Apply one place pack at each placement location. Space placements at intervals of 8 to 12 feet. Up to four place packs may be used at points of very high mouse or meadow vole activity.

Follow-Up: Adjust the amount of bait applied to the level of feeding expected at each bait placement location. Highest bait consumption is expected to occur on the first day or two after treatment. After several days, inspect bait placements and replenish bait at sites where there is heavy feeding or where there is continued evidence of rat, mouse or meadow vole activity. Maintain baiting for at least one week or until there no longer are fresh signs of rat, mouse or meadow vole activity or it becomes clear that the remaining rats, mice or meadow voles are not attracted to the bait.

Wearing barrier laminate gloves, collect and properly dispose of all dead rodents and leftover bait. To discourage reinfestation, limit sources of food, water, and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish them as needed.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

Pesticide Disposal: Dispose of wastes resulting from the use of this product in trash or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container.

Plastic Containers: Triple rinse (or equivalent) then offer for recycling or reconditioning; or puncture and dispose of container in a sanitary landfill; or by incineration.

Paper Containers: Dispose of empty container by placing in trash, at an approved waste disposal facility, or by incineration.

DISCLAIMER

DISCLAIMER: To the extent permitted by applicable law, seller makes no representation or warranty, either expressed or implied, for results due to misuse, improper handling or improper storage of this material. Nor does Seller assume any responsibility for injury to persons, crops, animals, soil or property arising out of misuse, improper handling or improper storage of this material.

OR

LIMITED WARRANTY

To the extent permitted by applicable law, Agrisel USA, Inc. makes no warranty concerning uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label. To the extent permitted by applicable law, Agrisel USA, Inc. shall not be liable for (1) any consequential, incidental or special damages related in any way to this product or its uses, or (2) any damages related in any way to resistance to pesticides.

OR

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

To the extent permitted by applicable law Agrisel USA, Inc. and Seller warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law this warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Agrisel USA, Inc., and Buyer and User assume the risk of any such use. To the extent permitted by applicable law, AGRISEL USA, INC. AND SELLER MAKE NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent permitted by applicable law, in no event shall Agrisel USA, Inc. or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF AGRISEL USA, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF THE AGRISEL USA, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Agrisel USA, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitations of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Agrisel USA, Inc.

For non-emergency (e.g., current product information), Call: *[to be provided at final printing]*

Outer Container Label
Agrisel Gladiator Place Pack Pellets
11/28/2016

Lot Number Placement:

Top of Plastic Pail
Seam of Plastic Pouch

Optional Marketing Statements:

Contains Bromethalin
Stop Feed Action
Helps Stop Damage Caused
by Norway Rats, Roof Rats,
Cotton Rats, Polynesian Rats,
House Mice, Eastern Harvest
Mice, Golden Mice, and
Meadow Voles.
Helps Stop Damage Caused
by Meadow Voles.
Helps Stop Damage Caused
by House Mice
Helps Stop Damage Caused
by Eastern Harvest Mice.
Helps Stop Damage Caused
by Golden Mice
Helps Stop Damage Caused
by Norway Rats.
Helps Stop Damage Caused
by Roof Rats.
Helps Stop Damage Caused
by Cotton Rats.
Helps Stop Damage Caused
by Polynesian Rats.

Agrisel Gladiator Place Pack Pellets

[Effective Indoor and Outdoor Control of Norway Rats, Roof Rats, Cotton Rats, Polynesian Rats, House Mice, Eastern Harvest Mice, Golden Mice, and Meadow Voles]

[Kills Norway Rats, Roof Rats, Cotton Rats, Polynesian Rats, House Mice, Eastern Harvest Mice, Golden Mice, and Meadow Voles]

[Norway Rats, Roof Rats, and House Mice usually consume a lethal dose in a single night's feeding, but it may take two or more days from time of bait consumption for them to die. Due to Stop Feed Action rats, mice and meadow voles will cease feeding after consuming a toxic dose.]

[This product is effective against anticoagulant-resistant Norway Rats, Roof Rats, and House Mice.]

[This product may only be used inside and within 100 feet of man-made structures or inside of transport vehicles (ships, trains, or aircraft).]

ACTIVE INGREDIENT:

Bromethalin

(CAS No. 63333-35-7).....0.01%

OTHER INGREDIENTS:.....99.99%

TOTAL:100.00%

EPA Reg. No. 72159-XX

EPA Est. No. XXXXX-XX XXX

KEEP OUT OF REACH OF CHILDREN CAUTION

Net Contents: 0.50 ounce (14 grams)

Net Weight: 0.50 ounce (14 grams)

It is Illegal to Sell This Place Pack Individually.

**Manufactured For:
Agrisel USA, Inc.
P.O. Box 3528
Suwanee, GA 30024**

FIRST AID	
HAVE LABEL WHEN OBTAINING TREATMENT ADVICE	
If Swallowed:	<ul style="list-style-type: none"> • Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice.
If in Eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice.
Have product container or label with you when calling a poison control center or doctor for treatment advice.	
TREATMENT FOR PET POISONING	
If animal eats bait, call veterinarian or 1-800-498-5743 at once.	
NOTE TO PHYSICIAN OR VETERINARIAN	
Contains the nerve poison Bromethalin. This is not an anticoagulant type rodenticide. For humans or animals ingesting bait and/or showing poisoning signs (such as muscle tremors, loss of hind limb use, or seizures for animals), limit absorption by either emesis or gastric lavage. Sublethal symptoms, if present, would be the result of cerebral edema and should be treated accordingly through administration of an osmotic diuretic and corticosteroid.	
For 24-hour emergency information on this product, call 1-800-498-5743 (US & Canada) or 1-651-523-0318 (all other areas).	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Keep away from children, domestic animals, and pets. Do not get in eyes, on skin, or on clothing. All handlers (including applicators) must wear long-sleeved shirt and barrier laminate gloves. Any person who retrieves carcasses or unused bait following application of this product must wear barrier laminate gloves.

User Safety Requirements

- Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.
- Remove PPE immediately after handling this product. Wash the outside of barrier laminate gloves before removing them.
- As soon as possible, wash hands thoroughly after applying the bait and before eating, drinking, chewing gum, using tobacco or using the toilet and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to mammals and birds. Dogs and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may also be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash water or rinsate.

Stop!

Read Entire Label on the Outer Package Including Precautions, Use Directions, and Storage and Disposal Text prior to Using This Product.

DISCLAIMER

DISCLAIMER: To the extent permitted by applicable law, seller makes no representation or warranty, either expressed or implied, for results due to misuse, improper handling or improper storage of this material. Nor does Seller assume any responsibility for injury to persons, crops, animals, soil or property arising out of misuse, improper handling or improper storage of this material.

OR**LIMITED WARRANTY**

To the extent permitted by applicable law, Agrisel USA, Inc. makes no warranty concerning uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label. To the extent permitted by applicable law, Agrisel USA, Inc. shall not be liable for (1) any consequential, incidental or special damages related in any way to this product or its uses, or (2) any damages related in any way to resistance to pesticides.

For non-emergency (e.g., current product information), Call: *[to be provided at final printing]*

Optional Marketing Statements:

Contains Bromethalin

Stop Feed Action

Helps Stop Damage Caused
by Norway Rats, Roof Rats,
Cotton Rats, Polynesian Rats,
House Mice, Eastern Harvest
Mice, Golden Mice, and
Meadow Voles.

Helps Stop Damage Caused
by Meadow Voles.

Helps Stop Damage Caused
by House Mice

Helps Stop Damage Caused
by Eastern Harvest Mice.

Helps Stop Damage Caused
by Golden Mice

Helps Stop Damage Caused
by Norway Rats.

Helps Stop Damage Caused
by Roof Rats.

Helps Stop Damage Caused
by Cotton Rats.

Helps Stop Damage Caused
by Polynesian Rats.

From: Arnold, Elyssa
Sent: Thursday, March 23, 2017 1:25 PM
To: Banks, Melody
Subject: RE: PM Review Requested - 72159-RI

The label submitted for 72159-RI dated November 29, 2016 was based on the label for

Elyssa Arnold, Acting Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0236
arnold.elyssa@epa.gov

From: Banks, Melody
Sent: Wednesday, March 22, 2017 11:01 AM
To: Arnold, Elyssa <Arnold.Elyssa@epa.gov>
Subject: PM Review Requested

BIOLOGIC CONSULTING, Inc.
agribusiness professionals

November 29, 2016

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

Attention: Ms. Venus Eagle (PM #01)

RE: "Agrisel Gladiator Place Pack Pellets", EPA Reg. No. 72159-XX
Application for Pesticide Registration – Re-Pack

Dear Ms. Eagle:

On behalf of Agrisel USA, Inc. we are submitting this Application for Pesticide Registration for the above mentioned product. The subject product is a 100% "re-pack" of [REDACTED]

The following documents are enclosed to process this registration:

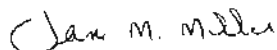
Volume 1 Administrative Materials

- Application for Pesticide Registration (EPA Form 8570-1)
- Formulator's Exemption Statement (EPA Form 8570-27)
- Confidential Statement of Formula (EPA Form 8570-4)
- Five (5) copies of draft labeling

This application for a new pesticide product will fall within the category on Table 4 - Registration Division: New Products, EPA No. R300; CR No. 44. The PRIA fee for this application is \$1,582.

Should you have any questions, or wish to reach me, please feel free to contact our office at 203-740-1200.

Sincerely,



Jane M. Miller
Agent to Agrisel USA, Inc.

115 Obtuse Hill Road • Brookfield, CT 06804
Tel: 203.740.1200 • Fax: 203.740.1220
Email: jmillers@biologicconsulting.com



Receipt

Your payment is complete

Pay.gov Tracking ID: 25V9OI74

Agency Tracking ID: 75138723614

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: \$1,582.00

Transaction Date: 11/30/2016 04:46:33 PM EST

Payment Date: 11/30/2016

Registration Number:

Company Name: Agrisel USA, Inc.

Company Number: 72159

Action Code: R300

Account Information

Cardholder Name: Jane M. Miller

Card Type: Visa

Card Number: *****6981

Email Confirmation Receipt

Confirmation Receipts have been emailed to:

jmiller@biologicconsulting.com



Receipt

Your payment is complete

Pay.gov Tracking ID: 25V9O174

Agency Tracking ID: 75138723614

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: \$1,582.00

Transaction Date: 11/30/2016 04:46:33 PM EST

Payment Date: 11/30/2016

Registration Number:

Company Name: Agrisel USA, Inc

Company Number: 72159

Action Code: R300

Account Information

Cardholder Name: Jane M. Miller

Card Type: Visa

Card Number: *****6981

Email Confirmation Receipt

Confirmation Receipts have been emailed to:

jmillers@biologicconsulting.com

TRANSFER JACKET FORM

Transfer This Jacket To: Melody Banks

Jacket #: 72159 - RT

This jacket was transferred from: Vernus Eagle

Date: 12/22/16

SD

Decision Seq: 524041 Action Code: R300,NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (A) ...

FFS Start Date: 22-Dec-2016 Tentative Ind: No FQPA Clock:

Due Date: 24-Apr-2017 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: 22-Dec-2016 FFS Original Decision: ...

Negotiated Due Date: 45-Day Due Date: 06-Feb-2017

Registrant Response Due Date: Predecisional Due Date: 10-Apr-2017 Add to Bundle? ☐

Current Status: PENDING (06-Dec-2016) Bundle ID:

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S:995661	Banks, Melody	... 72159-RT	24-Apr-2017	PENDING
100% repack of [REDACTED] labels need to be the same				

Viewing Record 1 of 1

Product ingredient source information may be entitled to confidential treatment

JACKETS (Fileroom Document Tracking System)
Requested Jackets Report (New Requests)

13-Dec-2016
8:32 AM
Adams, Teretha

Requested by : Eagle, Venus

Barcode : 20512

Agency : EPA Office : OCSP Program : OPP
Division : RD Branch : IVB3

Page 1 of 1

Requested on 13-Dec-2016 at 08:32 AM

Group Num: 365505

Jacket Barcode	Regulatory Case File #	Vol/Tot	Location	Status
9305661	72159-RT	1 / 1	File Rm: 67 / A / 01 / 1	Under Review (01-Dec-2016)
Total # of jackets requested :			1	

Completed:

TA

Date:

12/13/14

Time:

8:32

Eagle, Venus

21-Day Screen Completed by
Contractor

21-Day Expires on 12-22-16

Jacket # 72159-RT
MRID#

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHABER

12/22/16

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-1-16

Experts In-Processing Signature: B.B.

Date 12-7-16

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>72159-RT</u>		EPA Receipt Date: _____				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)		yes	no		
	<u>no inerts to review. 100% Re-Pack</u>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)					X
	Certificate and data matrix consistent					X
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		yes	no		
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)					X
5	a) Selective Method (Fee category experts use)		yes	no		
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5					X
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* Documentation: Pass / Fail
 - Required forms are complete

* Events: Pass / Fail
 - no Trends to review
 - no Re-Book

* PRN (13): Pass / Fail
 - no studies submitted

DL 12-8-16

* Overall Status: Pass / Fail

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 6, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-524041
EPA File Symbol or Registration Number: 72159-RT
Product Name: Agrisel Gladiator Place Pack Pellets
EPA Receipt Date: 01-Dec-2016
EPA Company Number: 72159
Company Name: AGRISEL USA, INC.

JANE M. MILLER
BIOLOGIC, INC.
REPRESENTING AGRISEL USA, INC.
115 OBTUSE HILL ROAD
BROOKFIELD, CT 06804

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code R300:
NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "N. J. H.", written over a horizontal line.

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{995661:~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

Receipt No.

S-

EPA File Symbol/Reg. No.

Pin-Punch Date:

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$

Parent/Child Decisions:

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer:  TIM CIARLO

Date:

Remarks:

Similarity Clinic Review Needed.

*100%
Respects*

DOCUMENTATION

Receipt for Section 3	
S: 995661	Milestone Email: jmillar@biologicconsulting.com
Regulatory Type: Product Registration - Section 3	Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No
Application Type: New Registration	Fee For Service: <input checked="" type="radio"/> Yes <input type="radio"/> No
Company: 72159 AGRISEL USA, INC.	Billable: <input checked="" type="radio"/> Yes <input type="radio"/> No
	<input checked="" type="checkbox"/> V
Risk Manager: Registration Division, Risk Management Team 1	
Product #: 72159-RT	Product Name: Agrisel Gladiator Place Pack Pellets
Override#:	
Me Too <input checked="" type="checkbox"/> Section3: [REDACTED]	Me Too Product Name: [REDACTED]
Application Date: 29-Nov-2016	OPP Rec'd Date: 01-Dec-2016
Front End Date: 01-Dec-2016	Risk Manager Send Date:
FFS Due Date:	Negotiated Due Date:
OPP Target Date:	
Fast Track: <input type="checkbox"/>	New Ingredient: <input type="checkbox"/>
Receipt Description: Portal submission pkg. #15769. Registration of a 100% re-pack.	
Form A <input type="checkbox"/> Signature Date:	Form B <input type="checkbox"/> Signature Date:
New Ingredient Request Date:	
New Ingredient Received Date:	
Receipt Content: CSF	
Electronic Label	
View/Edit	

DOCUMENTUM



Receipt

Your payment is complete

Pay.gov Tracking ID: 25V9OI74

Agency Tracking ID: 75138723614

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: \$1,582.00

Transaction Date: 11/30/2016 04:46:33 PM EST

Payment Date: 11/30/2016

Registration Number:

Company Name: Agrisel USA, Inc.

Company Number: 72159

Action Code: R300

Account Information

Cardholder Name: Jane M. Miller

Card Type: Visa

Card Number: *****6981


Email Confirmation Receipt

Confirmation Receipts have been emailed to:
jmillar@biologicconsulting.com

DOCUMENTUM

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080, Approval expires 2-28-95

	United States Environmental Protection Agency Washington, DC 20460	<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
---	---	--	-----------------------

Application for Pesticide - Section I

1. Company/Product Number 72159-XX	2. EPA Product Manager V. Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Agrisel Gladiator Place Pack Pellets	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) Agrisel USA, Inc. c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. [REDACTED] Product Name [REDACTED]

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
---	---

Explanation: Use additional page(s) if necessary. (For section I and Section II.)


This application for a new pesticide product will fall within the category on Table 4 - Registration Division: New Products. This product is further defined under EPA No. 300; CR No. 44. This product is a "Re-Pack". The PRIA fee for this application is \$1,582.

Jane Miller Tel: (203) 740-1200, Fax: (203) 740-1220, Email: jmillar@biologicconsulting.com

Section - III

1. Material This Product Will Be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
* Certification must be submitted If "Yes" Unit Packaging wgt. 0.50 oz. No. per container 128-1120		If "Yes" Package wgt. No. per container		<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4 lbs. through 35 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jane M. Miller	Title Agent	Telephone No. (Include Area Code) 203-740-1200	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Jane M. Miller		5. Date November 29, 2016	

BIOLOGIC CONSULTING, Inc.
agribusiness professionals

November 29, 2016

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

Attention: Ms. Venus Eagle (PM #01)

RE: "Agrisel Gladiator Place Pack Pellets", EPA Reg. No. 72159-XX
Application for Pesticide Registration – Re-Pack

Dear Ms. Eagle:

On behalf of Agrisel USA, Inc. we are submitting this Application for Pesticide Registration for the above mentioned product. The subject product is a 100% "re-pack" of [REDACTED]

The following documents are enclosed to process this registration:

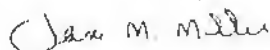
Volume 1 Administrative Materials

- Application for Pesticide Registration (EPA Form 8570-1)
- Formulator's Exemption Statement (EPA Form 8570-27)
- Confidential Statement of Formula (EPA Form 8570-4)
- Five (5) copies of draft labeling

This application for a new pesticide product will fall within the category on Table 4 - Registration Division: New Products, EPA No. R300; CR No. 44. The PRIA fee for this application is \$1,582.

Should you have any questions, or wish to reach me, please feel free to contact our office at 203-740-1200.

Sincerely,



Jane M. Miller
Agent to Agrisel USA, Inc.

115 Obtuse Hill Road • Brookfield, CT 06804
Tel: 203.740.1200 • Fax: 203.740.1220
Email: jmiller@biologicconsulting.com

DOCUMENTUM

